

HPA 505

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## **FREEDOM OF INFORMATION SUMMARY**

**Rimadyl® (carprofen) Chewable Tablets for Dogs**

**S/NADA 141-111**

**Pfizer Inc  
235 East 42<sup>nd</sup> Street  
New York, New York 10017**

FOIS 2

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**FREEDOM OF INFORMATION SUMMARY**

**I. GENERAL INFORMATION**

NADA Number: 141-111

Sponsor: Pfizer Inc  
235 East 42<sup>nd</sup> St.  
New York, NY 10017

Generic Name: carprofen

Trade Name: Rimadyl® Chewable Tablets

Marketing Status: Rx

Effect of Supplement: This supplement provides for flexibility in administration of the total daily dose of Rimadyl® Chewable Tablets. The drug may be administered orally at 2 milligrams per pound of body weight once daily or 1 milligram per pound of body weight twice daily.

**II. INDICATIONS FOR USE**

Rimadyl® is indicated for the relief of pain and inflammation associated with osteoarthritis in dogs.

**III. DOSAGE FORM, ROUTE OF ADMINISTRATION AND RECOMMENDED DOSAGE**

- A. Dosage Form: Rimadyl® is available as 25, 75, and 100 mg scored tablets.
- B. Route of Administration: Oral
- C. Recommended Dosage: The recommended dosage for oral administration to dogs is 2 mg/lb daily. The total daily dose may be administered as 2 mg/lb of body weight once daily or divided and administered as 1 mg/lb twice daily. Rimadyl® Chewable Tablets are scored and the dosage should be calculated in half-tablet increments. Tablets can be halved by placing the tablet on a hard surface and pressing down on both sides of the score. Rimadyl® Chewable Tablets are palatable and willingly consumed by most dogs. Tablets may be fed free choice or placed on food. Care should be taken to ensure that the dog consumes the complete dose.

**IV. EFFECTIVENESS**

Clinical effectiveness of the recommended dosage of 1 mg/lb body weight twice daily is contained in the original Freedom of Information Summary for NADA 141-111.

Clinical effectiveness of the recommended dosage of 2 mg/lb body weight once daily is contained in the supplement to the Freedom of Information Summary for NADA 141-053.

Reference is made to comparable relative bioavailability of Rimadyl® Caplets and Rimadyl® Chewable Tablets contained in original Freedom of Information for NADA 141-111. This study supports the comparable bioavailability of the caplet and chewable tablet when administered at a rate of 2 mg/lb total daily dose.

#### **Dosage Characterization**

Based on the approved 2 mg/lb total daily dose for Rimadyl® Caplets (NADA 141-053) and its comparable bioavailability to Rimadyl® Chewable Tablets (NADA 141-111), Rimadyl® Chewable tablets administered at a dosage of 2 mg/lb body weight once daily is expected to be effective for the relief of pain and inflammation associated with osteoarthritis in dogs. No additional clinical effectiveness data were required for approval.

#### **V. ANIMAL SAFETY**

Studies demonstrating the safety of Rimadyl® Chewable Tablets for use in dogs are contained in the original FOI summary for the approval for Rimadyl® Chewable Tablets (NADA 141-111) dated May 14, 1999. No new animal safety data were required for approval of this supplement.

#### **VI. HUMAN SAFETY**

Human Safety Relative to Food Consumption:

Data on human food safety, pertaining to consumption of drug residues in food, were not required for approval of this supplement. Rimadyl® Chewable Tablets are approved for use in dogs only.

Human Safety Relative to Possession, Handling and Administration:

Labeling contains adequate caution/warning statements.

#### **VII. AGENCY CONCLUSIONS**

The data in support of this NADA comply with the requirements of Section 512 of the Act and Section 514 of the implementing regulations. The data demonstrate that Rimadyl® Chewable Tablets (carprofen), when used under labeled conditions of use, are safe and effective.

Rimadyl® Chewable Tablets are restricted to use by or on the order of a licensed veterinarian because professional expertise is needed to diagnose canine osteoarthritis and to monitor response to treatment.

Under section 512(c)(2)(F)(iii) of the FFDCA, this approval for non-food producing animals does not qualify for marketing exclusivity because the supplemental application does not contain substantial evidence of the effectiveness of the drug involved, or any studies of animal safety required for the approval and conducted or sponsored by the applicant.

Pfizer Inc Patent Nos.      US 4,264,500 expires February 28, 2003  
   US 6,013,808 expires April 15, 2019

#### **VIII. LABELING**

Package insert  
Bottle

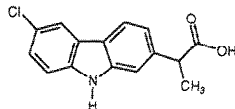
# RIMADYL®

(carprofen)

## Chewable Tablets

Non-steroidal anti-inflammatory drug  
For oral use in dogs only

**CATION:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.  
**DESCRIPTION:** Rimadyl (carprofen) is a non-steroidal anti-inflammatory drug (NSAID) of the propionic acid class that includes naproxen, naproxen, and ketoprofen. Carprofen is the nonproprietary designation for a substituted carbazole, 5-chloro- $\alpha$ -methyl- $\beta$ -carbolene-2-carboxylic acid. The empirical formula is  $C_{15}H_{11}ClNO_2$ , and the molecular weight 273.72. The chemical structure of carprofen is:



Carprofen is a white, crystalline compound. It is freely soluble in ethanol, but practically insoluble in water at 25°C.  
**CLINICAL PHARMACOLOGY:** Carprofen is a non-narcotic, non-steroidal anti-inflammatory agent with characteristic analgesic and antipyretic activity approximately equivalent to indomethacin in animal models.

The mechanism of action of carprofen, like that of other NSAIDs, is believed to be associated with the inhibition of cyclooxygenase activity. Two cyclooxygenase isoenzymes have been described in mammals: COX-1 (the constitutive cyclooxygenase, COX-1, synthesizes prostaglandins necessary for normal gastrointestinal and renal function. The inducible cyclooxygenase, COX-2, generates prostaglandins involved in inflammation. Inhibition of COX-1 is thought to be associated with gastrointestinal and renal toxicity while inhibition of COX-2 provides anti-inflammatory activity. The specificity of a particular NSAID for COX-2 versus COX-1 may vary from species to species.<sup>3</sup> In an *in vitro* study using canine cell cultures, carprofen demonstrated selective inhibition of COX-2 versus COX-1.<sup>4</sup> Clinical relevance of these data has not been shown. Carprofen has also been shown to inhibit the release of several prostanoids in two inflammatory cell systems: rat polymorphonuclear leukocytes (PMN) and human neutrophil synovial cells, reducing inhibition of acute (PMN system) and chronic (synovial cell system) inflammatory reactions.<sup>5</sup>

Several studies have demonstrated that carprofen has modulatory effects on both humoral and cellular immune responses.<sup>6-8</sup> Data also indicate that carprofen inhibits the production of osteoclast-activating factor (OAF), PGE<sub>2</sub>, and PGE<sub>1</sub> by its inhibitory effect on prostaglandin biosynthesis.<sup>9</sup>  
Based upon comparison with data obtained from *in vivo* studies, carprofen is rapidly and nearly completely absorbed (more than 90% bioavailable) when administered orally. Peak blood plasma concentrations are achieved in 1-2 hours after oral administration of 1, 5, and 25 mg/kg to dogs. The mean terminal half-life of carprofen is approximately 8 hours (range 4.5-8.8 hours) after single oral doses varying from 1-35 mg/kg of body weight. After a 100 mg single intravenous bolus dose, the mean elimination half-life was approximately 11.7 hours in the dog. Rimadyl is more than 99% bound to plasma protein and exhibits a very small volume of distribution. Carprofen is eliminated in the dog primarily by biotransformation in the liver followed by renal excretion of the resulting metabolites the ester glucuronide of carprofen and the ether glucuronides of 2-phenoxy metabolites: 7-hydroxy carprofen and 8-hydroxy carprofen in the feces (70-80%) and urine (10-20%). Some antiepileptic covariates of the drug is observed.

**INDICATIONS:** Rimadyl is indicated for the relief of pain and inflammation associated with osteoarthritis in dogs.  
**DOSEAGE AND ADMINISTRATION:** The recommended dosage for oral administration to dogs is 2 mg/kg of body weight daily. The total daily dose may be administered as 2 mg/kg of body weight once daily or divided and administered as 1 mg/kg twice daily. Rimadyl chewable tablets are scored and dosage should be calculated in half-tablet increments. Tablets can be broken by placing the tablet on a hard surface and pressing down on both sides of the score. Rimadyl chewable tablets are palatable and willingly consumed by most dogs when offered by the owner. Therefore, they may be fed by hand or placed on food. Care should be taken to ensure that the dog consumes the complete dose.

**PALATABILITY:** A controlled palatability study was conducted which demonstrated that Rimadyl chewable tablets were readily accepted and consumed on first offering by a majority of dogs.

**EFFECTIVENESS:** Separate placebo-controlled, masked, multicenter field studies confirmed the anti-inflammatory and analgesic effectiveness of Rimadyl in various breeds of dogs when dosed at 2 mg/kg of body weight once daily or when divided and administered at 1 mg/kg twice daily.

In these two field studies, dogs diagnosed with osteoarthritis showed significant improvement in lameness based on masked center and veterinarian evaluations when administered at the labeled dosages.

**ANIMAL SAFETY STUDIES:** Laboratory studies and clinical field trials have demonstrated that Rimadyl is well tolerated in dogs after oral administration.

In target animal safety studies, Rimadyl was administered orally to healthy Beagle dogs at 1, 3, and 5 mg/kg twice daily (1, 3, and 5 times the recommended total daily dose) for 12 consecutive days with no significant adverse reactions. Serum albumin for a single female dog receiving 5 mg/kg twice daily decreased to 2.1 g/dL after 2 weeks of treatment, returned to the pre-treatment value (2.6 g/dL) after 4 weeks of treatment, and was 2.3 g/dL at the final 6 week evaluation. Over the 6-week treatment period, black or bloody stools were observed in 4 of 11 incident treated with 1 mg/kg twice daily and in 1 of 12 incident treated with 1 mg/kg twice daily. Diarrhea of the colonic mucus was observed in 1 male that received 3 mg/kg twice daily.

Two of 8 dogs receiving 10 mg/kg orally twice daily (10 times the recommended total daily dose) for 14 days exhibited hepatomegaly. The mean albumin level in the dogs receiving 10 mg/kg was lower (2.38 g/dL) than that of 7 placebo control groups (2.58 and 2.63 g/dL, respectively). Three incidences of black or bloody stool were observed in 1 dog. Five of 8 dogs exhibited reddened areas of duodenal mucosa on gross pathological examination. Histologic examination of these areas revealed no evidence of ulceration, but did show minimal congestion of the lamina propria in 2 of the 5 dogs.

In separate safety studies lasting 13 and 52 weeks, respectively, dogs were administered orally up to 11.4 mg/kg/day (3 times the recommended total daily dose at 2 mg/kg of carprofen). In both studies, the drug was well tolerated clinically by all of the animals. No gross or histologic changes were seen in any of the treated animals. In both studies, dogs receiving the highest doses had average increases in serum L-alanine aminotransferase (ALT) of approximately 10 U.

In the 52 week study, minor dermatologic changes occurred in dogs in each of the treatment groups but not in the control dogs. The changes were described as slight redness or rash and were diagnosed as non-specific dermatitis. The possibility exists that these mild lesions were treatment related, but no dose relationship was observed.

**Clinical field studies** were conducted with 343 dogs of different breeds at the recommended dosage for 14 days (251 dogs were included in a study evaluating 1 mg/kg twice daily and 251 dogs were included in a separate study evaluating 2 mg/kg once daily). In both studies the drug was clinically well tolerated and the incidence of clinical adverse reactions for Rimadyl-treated animals was no higher than placebo-treated animals (placebo contained inactive ingredients found in Rimadyl). For animals receiving 1 mg/kg twice daily, the mean post-treatment serum ALT values were 1.1 U greater and 0.3 U less than pre-treatment values for dogs receiving Rimadyl and placebo, respectively. Differences were not statistically significant. For animals receiving 2 mg/kg once daily, the mean post-treatment serum ALT values were 4.5 U greater and 0.9 U less than pre-treatment values for dogs receiving Rimadyl and placebo, respectively. In the latter study, 3 Rimadyl treated dogs developed a 3- or greater increase in ALT (15 and 10 U) during the 14-day course of therapy. One placebo-treated dog had a greater than 2-fold increase in ALT. None of these animals showed clinical signs associated with the laboratory value changes. Changes in clinical laboratory values (hematology and clinical chemistry) were not considered clinically significant. The 1 mg/kg twice daily course of therapy was repeated as needed at 1 week intervals for 244 dogs, some for as long as 6 years.

**CONTRAINDICATIONS:** Rimadyl should not be used in dogs exhibiting previous hypersensitivity to carprofen or other NSAIDs.

**PRECAUTIONS:** As a class, cyclooxygenase inhibitory NSAIDs may be associated with gastrointestinal and renal toxicity. Effects may result from decreased prostaglandin production and inhibition of the enzyme cyclooxygenase which is responsible for the formation of prostaglandins from arachidonic acid.<sup>11-14</sup> When NSAIDs inhibit prostaglandins that cause inflammation they may also inhibit those prostaglandins which maintain normal homeostatic function. These anti-prostaglandin effects may result in clinically significant disease in patients with underlying or pre-existing disease more often than in healthy patients.<sup>15-17</sup> NSAID therapy could unmask occult disease which has previously been unapparent due to the absence of apparent clinical signs. Patients with underlying renal disease for example, may experience exacerbation or decompensation of their renal disease while on NSAID therapy.<sup>18-19</sup>

Carprofen is an NSAID, and as with others in this class, adverse reactions may occur with its use. The most frequently reported effects have been gastrointestinal signs. Events involving suppressed renal, hematologic, neurologic, dermatologic, and hepatic effects have also been reported. Patients of greatest risk for renal toxicity are

those that are dehydrated, on concomitant diuretic therapy, or those with renal, cardiovascular, and/or hepatic dysfunction. Since many NSAIDs possess the potential to induce gastrointestinal ulceration, concurrent use of Rimadyl with other anti-inflammatory drugs, such as corticosteroids and NSAIDs, should be avoided or very closely monitored. Sensitivity to drug-associated adverse reactions varies with the individual patient. For example, Rimadyl treatment was not associated with renal toxicity or gastrointestinal ulceration in a well-controlled safety studies of up to ten times the dose in dogs.

Rimadyl is not recommended for use in dogs with bleeding disorders (e.g., Von Willebrand's disease), as safety has not been established in dogs with these disorders. The safe use of Rimadyl in pregnant dogs, dogs used for breeding purposes, or in lactating bitches has not been established. Studies to determine the safety of Rimadyl when administered concomitantly with other protein-bound or similarly metabolized drugs have not been conducted. Drug compatibility should be monitored closely in patients requiring additional therapy.

Due to the palatable nature of Rimadyl Chewable Tablets, store out of reach of dogs in a secure location. Severe adverse reactions may occur if large quantities of tablets are ingested. If you suspect your dog has consumed Rimadyl chewable tablets above the labeled dose, please call your veterinarian for immediate assistance and notify Pfizer Animal Health (1-800-366-5288).

### INFORMATION FOR DOG OWNERS

Rimadyl, like other drugs of its class, is not free from adverse reactions. Owners should be advised of the potential for adverse reactions and be informed of the clinical signs associated with drug intolerance. Adverse reactions may include decreased appetite, vomiting, diarrhea, flat or tarry stools, increased water consumption, increased urination, pale gums due to anemia, yellowing of gums, skin or white of the eye due to jaundice, lethargy, incoordination, seizures, or behavioral changes. Severe adverse reactions associated with this drug class can occur without warning and in some situations result in death from adverse reactions. Owners should be advised to discuss these risks with their veterinarian and contact their veterinarian immediately if signs of intolerance are observed. The vast majority of patients with drug related adverse reactions have recovered when the signs are recognized, the drug is withdrawn, and veterinary care, if appropriate, is initiated. Owners should be advised of the importance of periodic follow up for all dogs during administration of any NSAID.

**WARNINGS:** Keep out of reach of children. Not for human use. Consult a physician in cases of accidental ingestion by humans. For use in dogs only. Do not use in cats.

All dogs should undergo a thorough history and physical examination before initiation of NSAID therapy. Appropriate laboratory tests to establish hematological and serum biochemical baseline data prior to, and periodically during, administration of any NSAID should be considered. Owners should be advised to observe for signs of potential drug toxicity (see Information for Dog Owners and Adverse Reactions).

**ADVERSE REACTIONS:** During investigational studies for the capsule formulation with twice daily administration of 1 mg/kg, no clinically significant adverse reactions were reported. Some clinical signs were observed during field studies (n=273) which were similar for carprofen capsule and placebo-treated dogs. Incidences of the following were observed in both groups: vomiting (4%), diarrhea (4%), flat stools in appetite (5%), lethargy (1.4%), behavioral changes (1%), and constipation (0.2%). The product vehicle served as control.

There were no serious adverse events reported during clinical field studies with once daily administration of 2 mg/kg. The following categories of abnormal health observations were reported. The product vehicle served as control.

Observation	Rimadyl (n=129)	Placebo (n=122)
Inappetence	1.6	1.5
Vomiting	3.1	4.0
Diarrhea/Salt stool	3.1	4.5
Behavior change	0.8	0.8
Dermatitis	0.8	0.8
PUPD	0.8	—
SAP increase	7.8	8.3
ALT increase	5.4	4.5
AST increase	2.3	0.8
BUN increase	3.1	1.6
Hypoproteinemia	1.2	0.1
Ketonuria	14.7	0.1

Clinical pathology parameters listed represent reports of increases from pre-treatment values; the use of clinical judgment is necessary to determine clinical relevance.

During investigational studies for the chewable tablet formulation, gastrointestinal signs were observed in some dogs. These signs included vomiting and soft stools.

**Post-Approval Experience:** Although not all adverse reactions are reported, the following adverse reactions are based on voluntary post-approval adverse drug experience reporting. The categories of adverse reactions are listed in decreasing order of frequency by body system.

**Gastrointestinal:** Vomiting, diarrhea, constipation, inappetence, melena, hematemesis, gastrointestinal ulceration, gastrointestinal bleeding, pancreatitis.

**Hepatic:** Inappetence, vomiting, jaundice, acute hepatic toxicity, hepatic enzyme elevation, abnormal liver function tests, hepatohemorrhagia, bilirubinuria, hyperbilirubinemia. Approximately one-fourth of hepatic reports were in Labrador Retrievers.

**Neurologic:** Ataxia, paresis, paralysis, seizures, vestibular signs, disorientation.

**Urinary:** Hematuria, polyuria, polydipsia, urinary incontinence, urinary tract infection, azotemia, acute renal failure, tubular abnormalities including acute tubular necrosis, renal tubular ectasia, glucosuria.

**Behavioral:** Sedation, lethargy, hyperactivity, restlessness, aggressiveness.

**Hematologic:** Immune-mediated hemolytic anemia, immune-mediated thrombocytopenia, blood loss anemia, aplasia.

**Dermatologic:** Pruritus, increased shedding, alopecia, asymmetric moist dermatitis (hot spots), necrotizing paronychia/paronychia, ventral ecchymosis.

**Immunologic or hypersensitivity:** Facial swelling, itches, erythema.

In rare situations, death has been associated with some of the adverse reactions listed above.

To report a suspected adverse reaction call 1-800-366-5288.

**STORAGE:** Store at controlled room temperature (15°-30°C/59°-86°F).

**HOW SUPPLIED:** Rimadyl chewable tablets are scored, and contain 25 mg, 75 mg, or 100 mg of carprofen per tablet. Each tablet size is packaged in bottles containing 14, 60, or 180 tablets.

**REFERENCES:**

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- Dines SH. Pathogenesis and pathophysiology of ischemic injury in cases of acute renal failure. *Compend for Cont Ed* 1(1), January 1994.
- Borche DM. Prostaglandins: Physiology and clinical implications. *Compend for Cont Ed* 1(1), November 1994.
- Robin ST. Nonsteroidal anti-inflammatory drugs, prostaglandins, and the kidney. *JAVMA* 1985, May 1986.
- For a copy of the Material Safety Data Sheet (MSDS) or to report adverse reactions call Pfizer Animal Health at 1-800-366-5288.

NADA #141-111, Approved by FDA

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**Pfizer**  
**Animal Health**  
Exton, PA 19341, USA  
Div. of Pfizer Inc  
NY, NY 10017



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## Dog Owner Information about RIMADYL® Chewable Tablets (carprofen)

Rimadyl® (pronounced "Rim-a-dill")

for Osteoarthritis Pain

Generic name: carprofen ("car-prō-fen")

This summary contains important information about Rimadyl. You should read this information before you start giving your dog Rimadyl and review it each time the prescription is refilled. This sheet is provided only as a summary and does not take the place of instructions from your veterinarian. Talk to your veterinarian if you do not understand any of this information or if you want to know more about Rimadyl.

### What is Rimadyl?

Rimadyl is a nonsteroidal anti-inflammatory drug (NSAID) that is used to reduce pain and inflammation (soreness) due to osteoarthritis in dogs. A licensed veterinarian must prescribe Rimadyl for your dog. It is available as a caplet and chewable tablet and is given to dogs by mouth.

Osteoarthritis (OA) is a painful condition caused by "wear and tear" of cartilage and other parts of the joints that may result in the following changes or signs in your dog:

- Limping or lameness
- Decreased activity or exercise (reluctance to stand, climb stairs, jump or run, or difficulty in performing these activities)
- Stiffness or decreased movement of joints

### What kind of results can I expect when my dog is on Rimadyl for OA?

While Rimadyl is not a cure for osteoarthritis, it can relieve the pain and inflammation of OA and improve your dog's mobility.

- Response varies from dog to dog but can be quite dramatic.
- In most dogs, improvement can be seen in a matter of days.
- If Rimadyl is discontinued or not given as directed, your dog's pain and inflammation may come back.

### Who should not take Rimadyl?

Your dog should not be given Rimadyl if he/she:

- Has had an allergic reaction to carprofen, the active ingredient of Rimadyl.
- Has had an allergic reaction to aspirin or other NSAIDs (for example etodolac or phenylbutazone) such as hives, facial swelling, or red or itchy skin.

**Rimadyl should be given to dogs only.** Cats should not be given Rimadyl. Call your veterinarian immediately if your cat receives Rimadyl. People should not take Rimadyl. Keep Rimadyl and all medicines out of reach of children. Call your physician immediately if you accidentally take Rimadyl.

### How to give Rimadyl to your dog.

Rimadyl should be given according to your veterinarian's instructions. Your veterinarian will tell you what amount of Rimadyl is right for your dog and for how long it should be given. Most dogs will take Rimadyl Chewable Tablets right out of your hand or the tablet can be placed in the mouth. Rimadyl may be given with or without food.

### What to tell/ask your veterinarian before giving Rimadyl.

Talk to your veterinarian about:

- The signs of OA you have observed (for example limping, stiffness).
- The importance of weight control and exercise in the management of OA.
- What tests might be done before Rimadyl is prescribed.
- How often your dog may need to be examined by your veterinarian.
- The risks and benefits of using Rimadyl.

Tell your veterinarian if your dog has ever had the following medical problems:

- Experienced side effects from Rimadyl or other NSAIDs, such as aspirin
- Digestive upset (vomiting and/or diarrhea)
- Liver disease
- Kidney disease
- A bleeding disorder (for example, Von Willebrand's disease)

Tell your veterinarian about:

- Any other medical problems or allergies that your dog has now or has had.
- All medicines that you are giving your dog or plan to give your dog, including those you can get without a prescription.

Tell your veterinarian if your dog is:

- Pregnant, nursing or if you plan to breed your dog.

### What are the possible side effects that may occur in my dog during Rimadyl therapy?

Rimadyl, like other drugs, may cause some side effects. Serious but rare side effects have been reported in dogs taking NSAIDs, including Rimadyl. Serious side effects can occur with or without warning and in rare situations result in death.

The most common NSAID-related side effects generally involve the stomach (such as bleeding ulcers), and liver or kidney problems. Look for the following side effects that can indicate your dog may be having a problem with Rimadyl or may have another medical problem:

- Decrease or increase in appetite
- Vomiting
- Change in bowel movements (such as diarrhea, or black, tarry or bloody stools)
- Change in behavior (such as decreased or increased activity level, incoordination, seizure or aggression)
- Yellowing of gums, skin, or whites of the eyes (jaundice)
- Change in drinking habits (frequency, amount consumed)
- Change in urination habits (frequency, color, or smell)
- Change in skin (redness, scabs, or scratching)

It is important to stop therapy and contact your veterinarian immediately if you think your dog has a medical problem or side effect from Rimadyl therapy. If you have additional questions about possible side effects, talk to your veterinarian.

### Can Rimadyl be given with other medicines?

Rimadyl should not be given with other NSAIDs (for example, aspirin, etodolac) or steroids (for example, cortisone, prednisone, dexamethasone, triamcinolone).

Tell your veterinarian about all medicines you have given your dog in the past, and any medicines that you are planning to give with Rimadyl. This should include other medicines that you can get without a prescription. Your veterinarian may want to check that all of your dog's medicines can be given together.

### What do I do in case my dog eats more than the prescribed amount of Rimadyl?

Contact your veterinarian immediately if your dog eats more than the prescribed amount of Rimadyl.

### How to store Rimadyl Chewable Tablets.

Rimadyl Chewable Tablets are designed to taste good to animals.

**Keep Rimadyl Chewable Tablets in a secured storage area out of the reach of your dog and other pets.** If your dog ingests more than your veterinarian prescribed, or if your other pets take Rimadyl Chewable Tablets, contact your veterinarian right away.

### What else should I know about Rimadyl?

This sheet provides a summary of information about Rimadyl. If you have any questions or concerns about Rimadyl or osteoarthritis pain, talk to your veterinarian.

As with all prescribed medicines, Rimadyl should only be given to the dog for which it was prescribed. It should be given to your dog only for the condition for which it was prescribed.

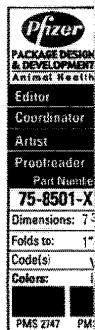
It is important to periodically discuss your dog's response to Rimadyl at regular check ups. Your veterinarian will best determine if your dog is responding as expected and if your dog should continue receiving Rimadyl.

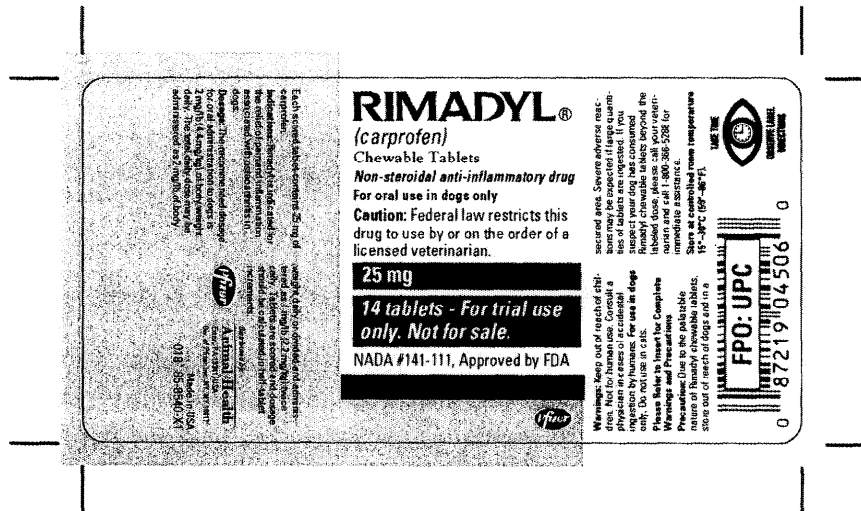
To report a suspected adverse reaction call Pfizer Animal Health at 1-800-366-5288.






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**Animal Health**  
Edison, PA 19341, USA  
Div. of Pfizer Inc.  
NY, NY 10017

www.rimadyl.com





 <b>PACKAGE DESIGN &amp; DEVELOPMENT</b> <b>Animal Health</b>	<b>Project Name</b>	<b>Part Number</b>	<b>Draft#</b>	<b>Date</b>	<b>Dimensions</b>
	<b>Rimadyl</b>	<b>85-8540-X1</b>	<b>1</b>	<b>29AUG01</b>	<b>1 7/8" x 3 3/4"</b>
	<b>Project Number</b>	<b>Country</b>	<b>Visual Code Bar(s)</b>		
	<b>1995</b>	<b>Die (CAD)#</b>	<b>Code(s) UPC</b>		
	<b>Editor</b>	<b>Michele Brettmann</b>	<b>Colors:</b>		
<b>Coordinator</b>	<b>Paige Hofpar</b>				
<b>Artist</b>	<b>Lois Nelson</b>	<b>PMS 116</b>	<b>PMS 330</b>	<b>PMS 286</b>	<b>PMS 254</b>
<b>Proofreader</b>	<b>Diane Mattison</b>				<b>Black</b>

**WARNING:** Keep out of reach of children. Not for human use. Consult a physician in cases of accidental ingestion. For use in dogs only. Do not use in cats.

**Please Refer to Insert for Complete Warnings and Precautions.**

**Precautions:** Due to the possible nature of Rimadyl chewable tablets, avoid use of each of dogs and in a second or 3rd.

Store at controlled room temperature 15°-30° C (59°-86° F).



Severe adverse reactions may be expected in dogs receiving this drug. In cases of overdose, avoid further use. Rimadyl chewable tablets beyond the labeled dose, please call your veterinarian and call 1-800-368-5286 for immediate assistance.

**RIMADYL®**  
(carprofen)  
**Chewable Tablets**

**Non-steroidal anti-inflammatory drug**

**For oral use in dogs only**

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**25 mg**

**60 tablets**

NADA #141-111, Approved by FDA



Each scored tablet contains 25 mg of carprofen.






**Indications:** Rimadyl is indicated for the relief of pain and inflammation associated with osteoarthritis in dogs.

**Dosage:** The recommended dosage for oral administration to dogs is 2 mg/lb (4.4 mg/kg) of body weight daily. The total daily dose may be administered as 2 mg/lb of body weight daily divided and administered in two (2) equal doses daily. Tablets are scored and dosage should be calculated in half-tablet increments.

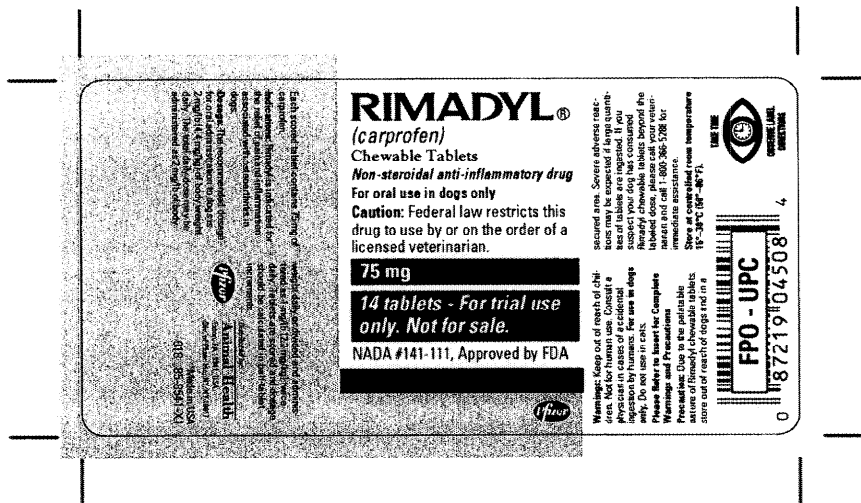
0 87219 03279 4







**Animal Health**  
Div. of Pfizer Inc.  
NY, NY 10017

Made in USA  
01E 85-8501-X4

 <b>PACKAGE DESIGN &amp; DEVELOPMENT</b> <b>Animal Health</b>	Project Name		Part Number	Draft#	Date	Dimensions
	Rimadyl		85-8501-X4	1	28AUG01	2 1/2" x 4 1/4"
	Project Number		Country		Visual Code Bar(s)	
	1995		Die (CAD)#		Code(s) UPC	
	Editor		Colors:		SKU: 8501000	
Coordinator	Paige Hofpar					
Artist	Lois Nelson		PMS 116	PMS 330	PMS 286	Black
Proofreader	Diane Mattison					





 <b>PACKAGE DESIGN &amp; DEVELOPMENT</b> <b>Animal Health</b>	Project Name	Part Number	Draft#	Date	Dimensions	
	<b>Rimadyl</b>	<b>85-8541-X1</b>	<b>1</b>	<b>29AUG01</b>	<b>1 7/8" x 3 3/4"</b>	
	Project Number	Country <b>USA</b>		Visual Code Bar(s)		
	<b>1995</b>	Die (CAD)#		Code(s) <b>UPC</b>		
	Editor	Michele Brettman	Colors: <span style="float: right;">SKU: 8541000</span>			
	Coordinator	Paige Hofpar	<div><div></div><div></div><div></div><div></div><div></div></div>			
Artist	Lois Nelson	PMS 116	PMS 330	PMS Rhodamine Red	PMS 254	Black
Proofreader	Diane Mattison					

**Warnings:** Keep out of reach of children. Not for human use. Consult a physician in cases of accidental ingestion by humans. For use in dogs only. Do not use in cats.

**Precautions:** Please Refer to Insert for Complete Warnings and Precautions.

**Precaution:** Due to the palatable nature of Rimadyl, chewable tablets, some out of reach of dogs and in a secured area. Severe adverse reactions may

be expected if large quantities of tablets are ingested. If you suspect your dog has consumed Rimadyl chewable tablets beyond the labeled doses, please call your veterinarian and call 1-800-999-5286 for immediate assistance. Store at controlled room temperature 15°-30°C (59°-86°F).

**RIMADYL®**  
(carprofen)

**Chewable Tablets**

**Non-steroidal anti-inflammatory drug**

**For oral use in dogs only**

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**75 mg**

**60 tablets**

NADA #141-111, Approved by FDA

**Pfizer**

body weight daily. The total daily dose may be administered as 2 mg/lb of body weight daily or divided and administered as 1 mg/lb (2.2 mg/kg) twice daily. Tablets are scored and dosage should be calculated in half-tablet increments.

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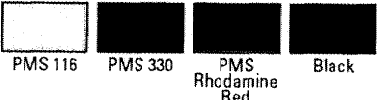
**Animal Health**  
Kroger, PA 15341, USA  
1000 Corporate Center  
NY, NY 10017






Made in USA  
018 85-8503-X4

Each scored tablet contains 75 mg of carprofen. **Indications:** Rimadyl is indicated for the relief of pain and inflammation associated with osteoarthritis in dogs. **Dosage:** The recommended dosage for oral administration to dogs is 2 mg/lb (4.4 mg/kg) of

**FPO:UPC**

0 87219 03283 1

 <b>PACKAGE DESIGN &amp; DEVELOPMENT</b> <b>Animal Health</b>	Project Name	Part Number	Draft#	Date	Dimensions
	<b>Rimadyl</b>	<b>85-8503-X4</b>	<b>1</b>	<b>04SEP01</b>	<b>3 1/16" x 4 1/2"</b>
	Project Number	Country	Visual Code Bar(s)		
	<b>1995</b>	<b>USA</b>	<b>Code(s) UPC</b>		
Editor	Michele Brettmann	Die (CAD)#	Colors:		
Coordinator	Paige Hofpar		SKU: 8503000		
Artist	Lois Nelson				
Proofreader	Diane Mattison				

<div></div> <div><b>PACKAGE DESIGN &amp; DEVELOPMENT</b></div> <div>Animal Health</div>	<b>Project Name</b>	<b>Part Number</b>	<b>Draft#</b>	<b>Date</b>	<b>Dimensions</b>
	<b>Rimadyl</b>	<b>85-8504-X4</b>	<b>1</b>	<b>29AUG01</b>	<b>3" x 7 1/2"</b>
	<b>Project Number</b>	<b>Country</b>	<b>Visual Code Bar(s)</b>		
	<b>1995</b>	<b>USA</b>	<b>Die (CAD)#</b> <b>Code(s) UPC</b>		
	<b>Editor</b>	<b>Michele Brettmann</b>	<b>Colors:</b> <span style="float: right;"><b>SKU: 8504000</b></span>		
<b>Coordinator</b>	<b>Paige Hofpar</b>				
<b>Artist</b>	<b>Lois Nelson</b>	PMS 116	PMS 330	PMS Rhodamine Red	Black
<b>Proofreader</b>	<b>Diane Mattison</b>				

**Warnings:** Keep out of reach of children. Not for human use. Consult a physician in cases of accidental ingestion by humans. For use in dogs only. Do not use in cats.

**Please Refer to Insert for Complete Warnings and Precautions.**

**Precaution:** Due to the palatable nature of Rimadyl chewable tablets, store out of reach of dogs and in a secured area. Severe

adverse reactions may be expected if large quantities of tablets are ingested. If you suspect your dog has consumed Rimadyl chewable tablets beyond the labeled dose, please call your veterinarian and call 1-800-366-5298 for immediate assistance.

**Store at controlled room temperature 15°-30°C (59°-86°F).**



# RIMADYL®

## (carprofen)

### Chewable Tablets

**Non-steroidal anti-inflammatory drug**

**For oral use in dogs only**

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**75 mg**

**180 tablets**

NADA #141-111, Approved by FDA



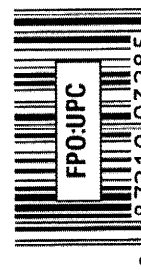
Each scored tablet contains 75 mg of carprofen.

**Indications:** Rimadyl is indicated for the relief of pain and inflammation associated with osteoarthritis in dogs.

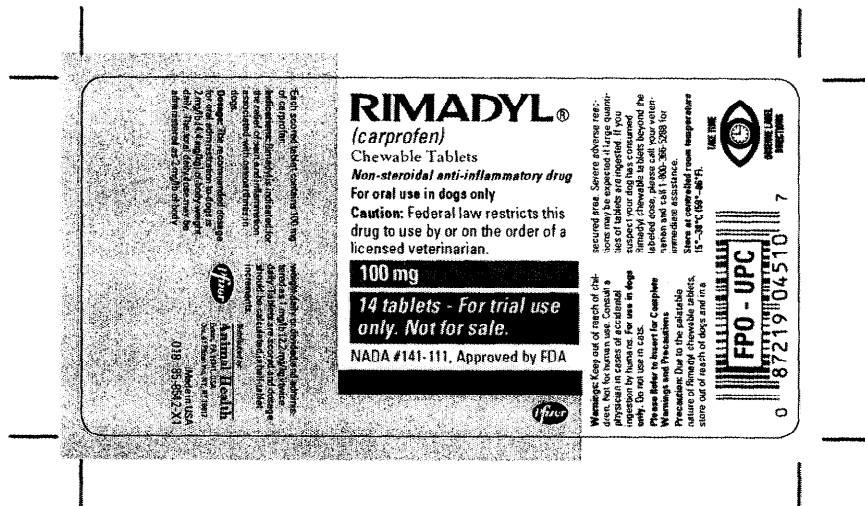
**Dosage:** The recommended dosage for oral administration to






dogs is 2 mg/lb (4.4 mg/kg) of body weight daily. The total daily dose may be administered as 2 mg/lb of body weight daily or divided and administered as 1 mg/lb (2.2 mg/kg) twice daily. Tablets are scored and dosage should be calculated in half-tablet increments.

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NY, NY 10017



Made in USA  
018 85-8504-X4



 <b>PACKAGE DESIGN &amp; DEVELOPMENT</b> <b>Animal Health</b>	Project Name		Part Number	Draft#	Date	Dimensions
	<b>Rimadyl</b>		<b>85-8542-X1</b>	<b>1</b>	<b>29AUG01</b>	<b>1 7/8" x 3 3/4"</b>
	Project Number		Country		Visual Code Bar(s)	
	1995		Die (CAD)#		Code(s) <b>UPC</b>	
			Colors:		SKU: 8542000	
<b>Editor</b>	Michele Brettmann					
<b>Coordinator</b>	Paige Hofpar		PMS 116	PMS 330	PMS 3275	PMS 254
<b>Artist</b>	Lois Nelson					Black
<b>Proofreader</b>	Diane Mattison					

**Warnings:** Keep out of reach of children. Not for human use. Consult a physician in cases of accidental ingestion by humans. For use in dogs only. Do not use in cats.

**Precautions:** Please refer to insert for Complete Warnings and Precautions. Due to the palatable nature of Rimadyl chewable tablets, store out of reach of dogs and in a secured area. Severe adverse reactions may

be associated with quantities of tablets are ingested. If you suspect your dog has consumed Rimadyl chewable tablets beyond the labeled dose, please call your veterinarian and call 1-800-368-5788 for immediate assistance. Store at controlled room temperature 65°-75°F (19°-24°C).



# RIMADYL® (carprofen)

**Chewable Tablets**

**Non-steroidal  
anti-inflammatory drug**

**For oral use in dogs only**

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**100 mg**

**60 tablets**

NADA #141-111, Approved by FDA

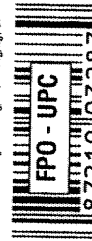


body weight daily. The total daily dose may be administered as 2 mg/lb (4.4 mg/kg) divided and administered as 1 mg/lb (2.2 mg/kg) twice daily. Tablets are scored and dosage should be calculated in half-tablet increments.

Each scored tablet contains 100 mg of carprofen. **Indications:** Rimadyl is indicated for the relief of pain and inflammation associated with osteoarthritis in dogs.

**Dosage:** The recommended dosage for oral administration to dogs is 2 mg/lb (4.4 mg/kg) of

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Made in USA  
018 85-8505-X4

 PACKAGE DESIGN & DEVELOPMENT Animal Health	Project Name	Part Number	Draft#	Date	Dimensions
	Rimadyl	85-8505-X4	1	29AUG01	3 1/16" x 4 1/2"
	Project Number	Country	Visual Code Bar(s)		
	1995	USA	Die (CAD)#	Code(s) UPC	
Editor	Michele Brettman	Colors:		SKU: 8505000	
Coordinator	Paige Hofpar				
Artist	Lois Nelson	PMS 116	PMS 330	PMS 3275	Black
Proofreader	Diane Mattison				

**Warnings:** Keep out of reach of children. Not for human use. Consult a physician in cases of accidental ingestion by humans. For use in dogs only. Do not use in cats.

**Please Refer to Insert for Complete Warnings and Precautions**

**Precaution:** Due to the palatable nature of Rimadyl chewable tablets, store out of reach of dogs and in a secured area. Severe

adverse reactions may be expected if large quantities of tablets are ingested. If you suspect your dog has consumed Rimadyl chewable tablets beyond the labeled dose, please call your veterinarian and call 1-800-366-5288 for immediate assistance.

**Store at controlled room temperature 15°-30°C (59°-86°F).**



# RIMADYL®

(carprofen)

## Chewable Tablets

**Non-steroidal anti-inflammatory drug**

**For oral use in dogs only**

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**100 mg**

**180 tablets**

NADA #141-111, Approved by FDA



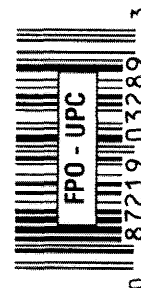
2 mg/lb (4.4 mg/kg) of body weight daily. The total daily dose may be administered as 2 mg/lb of body weight daily or divided and administered as 1 mg/lb (2.2 mg/kg) twice daily. Tablets are scored and dosage should be calculated in half-tablet increments.

Each scored tablet contains 100 mg of carprofen.






**Indications:** Rimadyl is indicated for the relief of pain and inflammation associated with osteoarthritis in dogs.

**Dosage:** The recommended dosage for oral administration to dogs is

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NY, NY 10017



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018 85-8506-X4

 <b>PACKAGE DESIGN &amp; DEVELOPMENT</b> <b>Animal Health</b>	<b>Project Name</b>	<b>Part Number</b>	<b>Draft#</b>	<b>Date</b>	<b>Dimensions</b>
	<b>Rimadyl</b>	<b>85-8506-X4</b>	<b>1</b>	<b>29AUG01</b>	<b>3 1/2" x 7 1/2"</b>
	<b>Project Number</b>	<b>Country</b>	<b>Visual Code Bar(s)</b>		
	<b>1995</b>	<b>Die (CAD)#</b>	<b>Code(s) UPC</b>		
	<b>Editor</b>	<b>Michele Brettmann</b>	<b>Colors:</b> <span style="float: right;">SKU: 8506000</span>		
	<b>Coordinator</b>	<b>Paige Hofpar</b>	<div></div>		
<b>Artist</b>	<b>Lois Nelson</b>	<b>PMS 116</b>	<b>PMS 330</b>	<b>PMS 3275</b>	<b>Black</b>
<b>Proofreader</b>	<b>Diane Mattison</b>				